

**CRITERIA FOR PRIOR AUTHORIZATION**

Direct Acting Hepatitis C Agents

<b>PROVIDER GROUP</b>	Pharmacy
<b>MANUAL GUIDELINES</b>	The following drug requires prior authorization: Simeprevir (Olysio®)

**CRITERIA FOR INITIAL PRIOR AUTHORIZATION OF ONE DIRECT ACTING AGENT:** (must meet all of the following)

*\*Patients new to the plan will be allowed to continue previous hepatitis C regimen (max of 12 weeks of Olysio therapy total)\**

- Patient must have a diagnosis of chronic hepatitis C
- Patient must have genotype 1 hepatitis C
- If patient has subtype 1a they must have a negative test for NS3-Q80k polymorphism
- Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist
- Patient must be 18 years of age or older
- Olysio must be used in combination with Peginterferon alfa and ribavirin
- Female patients must have a negative pregnancy test within 30 days prior to initiation of therapy and monthly during treatment with Olysio
- Patient must not have been on a previous or concurrent direct acting hepatitis C agent (i.e. concurrent therapy or previous trial with Victrelis, Incivek, Olysio, Sovaldi, Harvoni, Viekira Pak or other direct acting Hepatitis C agent)
- Dose must not exceed 1 capsule per day
- Patient must not have a history of illicit substance use or alcohol abuse within the past 6 months
- The patient must not have advanced and/or decompensated cirrhosis (moderate or severe hepatic impairment)
- Patient must have one of the following:
  - Advanced fibrosis (as defined by a Metavir score of F3)
  - Compensated cirrhosis
  - Liver transplant
  - Type 2 or 3 essential mixed cytoglobulinemia with end-organ manifestations (eg, vasculitis)
  - Proteinuria
  - Nephrotic syndrome
  - Membranoproliferative glomerulonephritis

**LENGTH OF INITIAL APPROVAL FOR ONE DIRECT ACTING AGENT** 12 weeks

Ribavirin and peg-interferon alfa are approved when using triple therapy with Olysio, if Olysio criteria are met.

**DISCONTINUATION CRITERIA FOR ONE DIRECT ACTING AGENT**

- Provider must submit HCV RNA level after treatment week 4, within 7 days, to prevent discontinuation of therapy
- Therapy will be discontinued if the HCV RNA level is greater than or equal to 25IU/mL after treatment week 4

**CRITERIA FOR INITIAL PRIOR AUTHORIZATION OF TWO DIRECT ACTING AGENTS:** (must meet all of the following)

- Patient must have a diagnosis of chronic hepatitis C (CHC) genotype 1
- Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist
- Patient must be 18 years of age or older
- Female patients must have a negative pregnancy test within 30 days prior to initiation of therapy and monthly during treatment with Sovaldi
- Patient must not have a history of illicit substance use or alcohol abuse within the past 6 months
- Dose must not exceed 1 capsule per day
- Patient must not be on previous or concurrent therapy with Victrelis, Incivek, Harvoni or Viekira Pak
- The patient must not have advanced and/or decompensated cirrhosis (moderate or severe hepatic impairment)
- Patient must have one of the following:
  - Advanced fibrosis (Metavir F3)
  - Compensated cirrhosis
  - Liver transplant
  - Type 2 or 3 essential mixed cytoglobulinemia with end-organ manifestations (eg, vasculitis)
  - Proteinuria
  - Nephrotic syndrome
  - Membranoproliferative glomerulonephritis
- Patient must not be on previous or concurrent therapy with Olysio unless the patient is interferon ineligible defined as one or more of the following:
  - Documented intolerance to IFN
  - Autoimmune hepatitis or other autoimmune disorder
  - Documented hypersensitivity to PEG or any of its components
  - Decompensated hepatic disease
  - Major uncontrolled depressive illness
  - A baseline neutrophil count below 1500 a baseline platelet count below 90,000 or baseline hemoglobin below 10 g/dL
  - A history of preexisting cardiac disease

**LENGTH OF INITIAL APPROVAL**      4 weeks

**RENEWAL CRITERIA FOR TWO DIRECT ACTING AGENTS:** (must the following)

- Prescriber must document adherence by patient of greater than or equal to 90% for both agents

**LENGTH OF RENEWAL APPROVALS**    4 weeks for a total of 12 weeks of treatment